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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,146	12/04/2003	Timothy A. Ringeisen	KN P 0146	1356
42016 7590 05/09/2008 KENSEY NASH CORPORATION 735 PENNSYLVANIA DRIVE EXTON, PA 19341			EXAMINER ROGERS, JAMES WILLIAM	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 05/09/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/729,146

Applicant(s)

RINGEISEN ET AL.

Examiner

JAMES W. ROGERS

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-26, 28-33, 36-50, 52-87 and 90-94 is/are pending in the application.
- 4a) Of the above claim(s) 66-73, 91 and 92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-26, 28-33, 36-50, 52-65, 74-87, 90, 93 and 94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22,31,39,42 and 66 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically the examiner could not find support within the specification as originally filed for the new limitations within claims 22,31 and 42 that states that the mixture is not constrained lateral to the compression direction. Applicants assert in their arguments that support is found within the affidavit and within the figures. However the examiner did not see any evidence within the figures that compression would not constrain the fibers lateral to the compression direction. Also an affidavit cannot be used as a disclosure of written support for new claim limitations; the limitations must be present within the original specification. Furthermore claims 39 and 66 both recite that the compressing force is exclusive of any rotation from a piston or mold, the examiner could also not find support within the original specification for such a limitation. Furthermore applicants have not noted within their remarks where such a limitation was supported.

Election by Original Presentation

In the office action filed 09/05/2007 the examiner withdrew by original presentation claim 90 for pertaining to an unelected invention. However within applicants arguments filed 02/08/2008, applicants assert that claim 90 reads on the elected invention of group II elected on 5/16/2006. The examiner concedes that indeed claim 90 does read on the elected invention and the previous withdrawal by original presentation for claim 90 is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-26,28-33,36-45,47-49,52-53,61-65,74-77,80-81,84,87, 90 and 92-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone (US 5,158,574), for the reasons set forth in the previous office action filed 09/05/2007.

Regarding claim 90, since this claim is essentially the same as claim 22 without the product by process limitation as noted in the previous office actions the product of claim 22 and thus necessarily claim 90 are met by the teachings of Stone. Regarding new claims 93 and 94 since the claims are drawn to an implantable device or a compressed fibrous matrix the limitation on the process to produce the article was not considered limiting by the examiner. As noted in the previous office actions all of the limitations for the materials of claims 39 and 42 are met. Therefore the process to produce those materials does not limit the claim in such a way as to preclude the

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materials of Stone even if the methods to produce the materials are different. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Regarding claims 36 and 37 since the materials taught by Stone are within the claimed scope of applicants claims it is inherent that the same material will be able to provide for the same intended use, thus the materials of Stone would be capable of swelling upon exposure to bodily fluid and they would be able to accept a suture.

Claims 22-26,28-30,36-48,52-65,74-84,87,90 and 92-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (US 2002/0127270), for the reasons set forth in the previous office action filed 09/05/2007.

Regarding claim 90, since this claim is essentially the same as claim 22 without the product by process limitation as noted in the previous office actions the product of claim 22 and as a result claim 90 as well are met by the teachings of Li. Regarding new claims 93 and 94 since the claims are drawn to an implantable device or a compressed fibrous matrix the limitations on the process to produce the articles are not considered limiting by the examiner. As noted in the previous office actions all of the limitations for the materials of claims 39 and 42 are met. Therefore the claimed process to produce those materials does not limit the claim in such a way to preclude the materials of Li

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even if the methods to produce the materials are different. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Regarding claim 36 since the materials taught by Li are within the claimed scope of applicants claims it is inherent that the same material will be able to provide for the same intended use, thus the materials of Li would be capable of swelling upon exposure to bodily fluid.

Response to Arguments

Applicant's arguments filed 02/08/2008 have been fully considered but they are not persuasive.

Applicants assert that the claimed method steps clearly differentiate over the device fabrication methods of Stone and Li because applicants method steps comprise compressing a fibrous slurry, the compression being without rotation of a piston or mold and without constraint in directions lateral to the direction of compression. Applicants assert both Li and Stone incorporate rotation as part of their respective fabrication processes. Applicants state that they shift the burden to the office to show that the respective devices are the same. Applicants also assert that neither Stone nor Li disclose or suggest the claimed plates of the independent claims 22,31,39 and 42. Applicants also note that in the previous declaration co-inventor Ringeisen states that

rotation of the piston or mold as in Stone would disrupt plate formation. Further applicants submit that Li does not disclose or suggest the claimed fluid planes defined as a space between plates. Applicants state that in contrast Li would seemingly have a single fluid plane defined by the laminated layers or by each pair of laminated layers. Applicants surmise that such a fluid plane would not exist as multiple fissures located randomly within the structure, but instead would be a single uniform fluid plane.

The examiner respectfully disagrees with the assertions above. Firstly applicants claimed invention is to an implantable device and a fibrous network, not a method of fabrication. As already noted in the previous office actions since Li and Stone read on applicants claimed invention all the claim limitations rejected above are considered met. Since we are discussing the claimed product we must compare the implants described in the art with applicants claimed invention. The limitations that the implants comprise fibers, which are at least partially aligned into a plurality of plates, is simply not found very limiting by the examiner. Since the cited Stone and Li references describe implantable fibers, which are produced by compressing it is inherent that the fibers must at the very least form some plates of at least some of the fibers when they are compressed. Also at least Li states that the orientation of the fibers is in one direction, thus meeting the limitation of at least partial alignment. Applicants cannot exclude other processes to make polymer implants just because of comments within their remarks/arguments, it must be explicitly excluded from the claims, however the claims are drawn to a product therefore the method to produce the product is of little relevance as long as the claimed product is met by the prior art. It was previously noted by the

examiner that the declaration of Ringeisen was an opinion type of declaration that did not show any data to support the conclusion that compression as taught within Li or Stone would not lead to at least some orientation of the fibers and the formation of at least some plates. Regarding applicants assertions on Li, clearly the reference states that the bipolymeric membrane is formed by compressing an aqueous solution containing the fibers, clearly there would be some aqueous solution that would be trapped between the layers of fibers or within pockets of the compressed fibers, thus meeting fluid planes located in a space between plates.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22-26,28-33,36-50,52-65,74-87,90 and 93-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (US 5,158,574) in view of Li et al. (US 2002/0127270) and in further view of Haldimann (US 6,428,576 B1, disclosed previously), for the reasons set forth in the previous office action filed 09/05/2007.

Response to Arguments

Applicant's arguments filed 02/08/2008 have been fully considered but they are not persuasive.

Applicants assert that Li discloses laminating layers in different directions, thus it is deliberate orientation and is different then independent orientation which would suggest the plates can have any orientation.

The relevance of this assertion is unclear, applicants do not claim at least within the independent claims that the plates have an independent orientation as applicants assert. Nor have applicants pointed out which dependent claims have the limitation that the plates have an independent orientation. The examiner assumes the applicants are arguing in regards to dependent claims 45 and 46 which state that the plates are randomly oriented or each plate is independent of the orientation of fibers within adjacent plates. However while Li does disclose the conscious orientation of fibers this step is not mandatory, thus in absence of the conscious and deliberate orientation of the fiber membranes the membranes would essentially be random as to their orientation of the alignment of fibers.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618